

## REMARKS

By the present amendment and remarks, Applicant respectfully requests reconsideration of the outstanding Office Action and allowance of the present application.

### Summary of Amendments

By the foregoing amendment, claims 23, 25-27, 29-30, 33, and 38-39 are amended, whereby claims 23-39 remain pending. Of the pending claims, claim 23 is independent.

Claim 23 is amended to further clarify the invention. Support for the amendment to claim 23 can be found in the originally filed specification and claims, and is inherent therein. For example, support for the amendment can be found at Figure 3, page 3, lines 7-19, and page 10, line 32 – page 11, line 6 of the specification. Claims 23, 25-27, 29-30, 33, and 38-39 are also amended to remove “means” language from the claims. Applicant submits that no new matter has been added.

Further, any amendments to the claims which have been made in this response and which have not been specifically noted to overcome a rejection based upon the prior art, should be considered to have been made for a purpose unrelated to patentability, and no estoppel should be deemed to attach thereto.

**Summary of Telephonic Interview – December 19, 2006**

Applicant thanks Examiner's Kristin Rogers and Max Hindenburg for taking the time to participate in a telephonic interview on December 19, 2006, with Applicants' Representative, Wesley Nicolas (USPTO Reg. No. 56,129).

During the interview, Applicant discussed the rejections noted in the Office Action dated July 24, 2006. Specifically, Applicant inquired as to the previously amended title, and provided arguments as to why the 35 U.S.C. § 103 rejections should be withdrawn. In particular, Applicant discussed the differences between the secondary document of BUCALO in comparison to the claims.

Applicant submits that Examiner's characterization of the substance of the interview as noted in the Interview Summary Form mailed December 29, 2006 is complete, and no further supplementation or clarification is required.

**RESPONSE TO CLAIM REJECTIONS****1. Rejections under 35 U.S.C. § 103(a)**

The Office Action contains the following rejections under 35 U.S.C. § 103(a):

- (a) Claims 23-27, 29-34 and 38-39 are rejected under 35 U.S.C. § 103(a) as being unpatentable over HENDRIKX (EP 1060662), and further in view of BUCALO (US 5,267,572);
- (b) Claim 28 is rejected under 35 U.S.C. § 103(a) as being unpatentable over HENDRIKX in view of BUCALO, and further in view of MOLOMUT (US 3,224,434);

(c) Claims 35-36 are rejected under 35 U.S.C. § 103(a) as being unpatentable over HENDRIKX in view of BUCALO, and further in view of RITCHEY (US 6,145,225).

(d) Claim 37 is rejected under 35 U.S.C. § 103(a) as being unpatentable over HENDRIKX, BUCALO, and RITCHEY, and further in view of BLACK (US 6,239,737).

In response, Applicant respectfully disagrees with the Office's conclusions regarding obviousness. Therefore, Applicant respectfully requests withdrawal of the obviousness rejections in view of the foregoing amendment and following remarks. Applicant respectfully submits that a *prima facie* case of obviousness is not established by HENDRIKX in view of BUCALO for at least the following reasons.

A *prima facie* case of obviousness requires:

- 1) the presence of all claimed elements,
- 2) the motivation to combine the separate reference teachings, and
- 3) a reasonable expectation of success.

The Office Action fails to establish any of these requirements.

**(1) The Combination of Cited Documents Fails to Disclose All Elements of the Present Claims**

First, regarding the presence of all claimed elements, Applicant respectfully submits that the requirement that all claimed elements be taught or suggested in the cited document(s), and this requirement has not been met.

For instance, even if the teachings of the cited documents in rejections (a) – (d) were combined as suggested by the Office Action, the present invention would not result.<sup>1</sup> In this regard, Applicant submits that BUCALO fails to specifically teach at least “as the male and female portions are brought together and in turn to be received within, and to seal the biological sample therein providing a sealed sample receiving space” or “the sample removal system having provided therein an amount of sample preparative or preservative that is available to the biological sample within the sealed sample receiving space” as required by claim 23. In contrast to the present claims, BUCALO discloses a separate preservative container which is not sealed (*see, e.g.*, Fig. 7, numeral 26), in which the biopsy instrument is placed after performing the biopsy.

Applicant respectfully submits that, to establish a *prima facie* case of obviousness, the U.S. Patent and Trademark Office bears the burden of showing that all of the claimed elements would be present in the combination. The Office Action fails to make that showing. Applicant respectfully submits that BUCALO’s preservative container 26 is not, and cannot be an integral part of the sampling device because it is separate therefrom. Moreover, BUCALO’s preservative container 26 is not sealed because it contains an opened top (*see, e.g.*, top of 26 in Fig. 7). Accordingly, since BUCALO does not cure the deficiencies of HENDRIKX, and the combination of HENDRIKX and BUCALO does not disclose or suggest all the recitations of the present claims;

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<sup>1</sup> Applicant notes that the secondary document of BUCALO has been used in all of the rejections under 35 U.S.C. § 103.

wherefore, all rejections that rely on the combination of HENDRIKX and BUCALO should be withdrawn.

Therefore, Applicant respectfully requests withdrawal of the 35 U.S.C. § 103 rejections of claims 23-39.

**(2) The Cited Documents Fail to Provide Motivation to Arrive at the Claimed Invention**

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Second, regarding motivation to combine the separate document teachings, to properly establish a *prima facie* case of obviousness, even assuming, *arguendo*, that the rejection is based on a proper combination, the combined teachings must disclose all of the recitations of the rejected claims and the cited document(s) must contain some suggestion or motivation for such combination. Applicants respectfully submit that the cited documents fail to provide specific motivation to arrive at the claimed invention. Moreover, pointing to the disclosure in Applicants' specification is improper, especially when Applicants' disclosure teaches away from the present invention. Thus, Applicants respectfully submit that mere statements that it would have been obvious to one of ordinary skill in the art without pointing to specific support in the cited document **is not sufficient** to satisfy the *prima facie* case of obviousness.

The Office Action relies upon the secondary document of BUCALO alleging the disclosure of a sample removal system with preservative liquid for the purpose of preparing and preserving the biological tissue specimen. The Office Action states that a person of skill in the art would have combined BUCALO with HENDRIKX, "since such

modification *would* maintain the integrity of a biological sample for future experimental analysis” (Office Action, page 4, lines 16-17, emphasis added), yet cites to nothing where this motivation is found. Applicants respectfully submit, however, that the Office pays lip-service to concept of motivation but does nothing more.

The requirement of a showing of motivation is intended to prevent hindsight analysis of an Applicants’ claimed invention. It is intended to prevent the Office from simply choosing separate teachings that *can* be combined to make an Applicants’ claimed invention, without some additional underlying suggestion for actually making the combination. It is intended to prevent the Patent Office from combining teachings so as to arrive at an Applicants’ claimed invention, then to state, “Voila! The improvement is in the combination!” It is intended to prevent exactly the reasoning that the outstanding Office Action sets forth.

The Office Action fails to provide any reason why a person of skill in the art would have *wanted* to maintain the integrity of the biological sample. BUCALO discloses nothing of this sort, and even depicts an open preservative container (*see, e.g.,* Fig. 7, numeral 26) which cannot be said to “maintain the integrity of the biological sample” as asserted in the Office Action. Applicants respectfully submit that the present specification cannot serve as the motivation to combine reference teachings and that the motivation to combine teachings must come from the prior art. The Office Action fails to set forth any reason at all of why Applicant’s sealed sample receiving space would be an *improvement* on any of the particular applications disclosed in BUCALO (or

HENDRIKX). Thus, without more, the Office Action fails to satisfy the second of three requirements for making a *prima facie* case of obviousness.

Therefore, for at least the foregoing reasons, Applicants respectfully submit that the presently claimed sampling device would not have been obvious in view of the cited documents. Accordingly, Applicants respectfully request withdrawal of the 35 U.S.C. § 103 rejections of claims 23-39.

**(3) There Would Have Been no Expectation of Success**

Finally, despite the assertions in the Office Action, there would have been no expectation of success of achieving the specific recitations of the present claims. There is no reason to believe that Applicant's particularly claimed sampling device would have resulted by combining the cited documents in rejections (a) – (d).

As noted above, the Office Action suggests that a person of ordinary skill in the art would have combined the teachings of the secondary document of BUCALO with the primary document of HENDRIKX, with an expectation that “such modification *would* maintain the integrity of a biological sample for future experimental analysis” (Office Action, page 4, lines 16-17, emphasis added). However, Applicants respectfully submit that there is no expectation of success in achieving the nebulous *improvement* the Office Action suggests, without some additional explanation by the Office of what such improvement is, or why it is desirable. For this reason as well, a *prima facie* case of obviousness cannot result here.

In particular, Applicants note that in contrast with the present claims, BUCALO discloses a biopsy instrument that does not go fully through the specimen, whereas the present invention completely pierces the specimen (e.g., animal ear). Moreover, as noted above, BUCALO discloses an open preservative container (See, e.g., Fig. 7, numeral 26) which cannot be said to “maintain the integrity of the biological sample” as asserted in the Office Action. Therefore, Applicant respectfully submits that there is no expectation that its particularly claimed sampling device would have resulted by combining the cited documents in rejections (a) – (d).

With regard to rejection (b) (claim 28) as being rejected over HENDRIKX and BUCALO in view of MOLUMUT, Applicant notes that MOLUMUT does not involve cutting tissue from specimens, and is therefore not properly combinable with HENDRIKX and BUCALO. Instead, MOLUMUT regards cutting the patient to remove tissue to be a disadvantage. (See col. 1, lines 21-23). Further, MOLUMUT’s device operates on the principle of a vacuum cleaner, thereby obtaining samples from open body cavities by suction. (See col. 3, lines 21-39). In contrast, the present invention uses a porous material over an inlet or outlet of the (sample) chamber, but does not contain both an inlet and outlet for passage of material as does MOLUMUT.

Therefore, in view of the numerous differences as noted above, Applicant respectfully submits that the combinations of the cited documents are incompatible, and there can be no expectation of success in achieving Applicants’ claimed invention.

Therefore, Applicants respectfully submit that the presently claimed sampling device would not have been obvious in view of the combination of the cited documents in



rejections (a) – (d). Accordingly, Applicants respectfully request withdrawal of the 35 U.S.C. § 103 rejections.

### **Application is Allowable**

Thus, Applicant respectfully submits that each and every pending claim of the present invention meets the requirements for patentability under 35 U.S.C. §§ 102 and 103, and respectfully request the Examiner to indicate allowance of each and every pending claim of the present invention.

### **CONCLUSION**


In view of the foregoing, it is submitted that none of the cited documents of record, either taken alone or in any proper combination thereof, anticipates or renders obvious the Applicants' invention, as recited in each of claims 23-39. In addition, the applied documents of record have been discussed and distinguished, while significant claimed features of the present invention have been pointed out.

Further, any amendments to the claims which have been made in this response and which have not been specifically noted to overcome a rejection based upon the prior art, should be considered to have been made for a purpose unrelated to patentability, and no estoppel should be deemed to attach thereto.

Accordingly, reconsideration of the outstanding Office Action and allowance of the present application and all the claims therein are respectfully requested and now believed to be appropriate.

Should there be any questions, the Examiner is invited to contact the undersigned at the below-listed telephone number.

Respectfully Submitted,  
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